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K003303
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510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama
President

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Date Submitted: October 18, 2000

Device Identification:

Trade Name:	IM-5B Microinjector
Common Name:	Microinjector
Classification Name:	Assisted Reproduction Micromanipulators and Microinjectors (21 CFR, 884.6150)

Predicate Device:

IM-9A Microinjector, Premarket Notification 510(k) Number: K001911

Device Description:

The IM-5B Microinjector is used to inject solutions into organisms, aspirate fluid samples from tissues or hold cells and eggs by aspiration onto the end of a holding pipette. It is easy to use simply by turning the Control Knob clockwise for injection and counterclockwise for aspiration.

The IM-5B Microinjector is a component part of a micromanipulator system. For ICSI procedure using the IM-5B, the micromanipulator system requires:

1 unit of the manipulator mounting adaptor (for mounting the micromanipulators to the microscope);
2 units of the coarse manipulator (for coarse positioning);
2 units of the fine micromanipulator (for fine positioning);
2 units of the joint unit (for holding the pipette holder)

2 units of Microinjector (2 units of IM-5B Microinjector) (one for holding pipette and one for injecting pipette);
1 holding pipette;
and 1 injecting pipette.

Examples of roles the IM-5B plays in the ICSI would be:
- holding an oocyte
- aspirating a sperm into the injection pipette
- injecting a sperm into an oocyte

Intended Use:

The IM-5B Microinjector is used to inject solutions into organisms, aspirate fluid samples from tissues or hold cells and eggs by aspiration onto the end of a holding pipette.

Substantial Equivalence:

Narishige Co., Ltd. claims IM-5B Microinjector as substantially equivalent to Predicate IM-9A Microinjector, Premarket Notification 510(k) Number: K001911.

Technological Characteristic:

The IM-5B Microinjector is a manually operated screw-driven microinjector.

The specification of the IM-5B is summarized in the table below.

Maximum Movement Range of the Plunger	40mm
The Distance the Plunger Travels by One Rotation of the Control Knob	Approx. 500μm
The Amount Controlled by One Rotation of the Control Knob	Approx. 40μl

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Mitsuko Yoneyama
President
Narishige Co., Ltd.
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Tokyo 157-0062
JAPAN

Re: K003303
IM-5B Microinjector
Dated: October 18, 2000
Received: October 20, 2000
Regulatory Class: II
21 CFR §884.6150/Procode: 85 MQJ

Dear Ms. Yoneyama:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003303

Device Name: **IM-5B Microinjector**

Indications For Use:

The IM-5B Microinjector is used to inject solutions into organisms, aspirate fluid samples from tissues or hold cells and eggs by aspiration onto the end of a holding pipette.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David A. Syverson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003303

Prescription Use ✓
(Per 21 CFR 801.109)